REMARKS

Applicant requests reconsideration of the application in view of the foregoing amendments and the discussion that follows. The status of the claims as of this response is as follows: Claims 1-60 are pending. Claims 1, 6, 8, 12, 14, 19, 23, 48, 53, 58 and 60 have been amended herein and Claim 7 has been canceled.

The Amendments

Claims 1, 8, 14, 23, 48, 53, 58 and 60 were amended to delete the word "about."

Claim 1 was also amended to incorporate the language of Claim 7.

Claims 6, 19, 53 and 60 were amended to refer to a protein immunogenic carrier. Support therefor is in the specification, for example, original Claims 6, 19, 53 and 60.

Claim 8 was also amended to recite "wherein the compound is a stereoisomeric mixture that comprises at least 51% of one stereoisomeric form over the other." Support therefor is in the specification, for example, page 7, lines 16-18.

Claim 12 was amended to recite that the stereoisomeric mixture comprises at least 90% of one stereoisomeric form over the other. Support therefor is in the specification, for example, page 7, lines 16-19.

Rejection under 35 U.S.C. 112

Claims 1-60 were rejected under the second paragraph of the above code section as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Office Action contends that it is not clear what "immunogenic carrier" or "label" is encompassed by the terms "non-poly(amino acid) label" and "non-poly(amino acid) immunogenic carrier" in Claims 1, 8, 13, 14, 23, 48, 53, 58 and 60. The specification (paragraph bridging pages 10-11), for example, discusses "non-poly(amino acid) labels" and "poly(amino acid) labels" such as proteins. Immunogenic carriers, including both poly(amino acid) (or protein) immunogenic carriers and non-poly(amino acid) immunogenic carriers, which are differentiated from poly(amino acid) (or protein) immunogenic carriers, are discussed in detail in, for example, page 11,

line 18, to page 12, line 6. In light of Applicant's disclosure, one skilled in the art would have ample understanding of what is encompassed by the above terms.

With respect to Claims 1,13, 14, 23, 48, 53, 58 and 60, the Office Action alleges that it is not clear what is encompassed by the term "functional group." Applicant's disclosure contains a detailed discussion of common functionalities at, for example, page 9, lines 4-21. In light of Applicant's disclosure, one skilled in the art would have ample understanding of what is encompassed by the above phrase.

Claims 1, 13, 14, 23, 48, 53, 58 and 60 were rejected for recitation of the term "protecting group". The Office Action contends that it is not clear what is encompassed by this term because "protecting group" is a general term which includes numerous groups for protection of functional groups -OH, -NH, -SH, -COOH and -CO. Therefore, concludes the Office Action, these claims are vague and indefinite for not clearly defining the protecting group.

First, the term "protecting group" is used in the claims for a substituent on either an -N-, -O- or -S- functionality. Second, the specification discusses in detail what is meant by the term. See, for example, page 20, lines 11-22. Finally, the term is well-known to those skilled in the art.

With respect to claims 30, 32, 40, 48 and 58, the Office Action alleges that it is not clear whether the "antibody" used in the method is raised against a compound of what formula, i.e., against what hapten immunogen conjugate? In response, in each of the above claims, a label conjugate or an enzyme label conjugate in accordance with embodiments of the present invention is recited. Consequently, any antibody specific for the designated compound is intended to be included in the claimed methods since the label conjugate and not the antibody determine the patentability of the methods of these claims. In addition, antibodies are discussed in detail in the specification, for example, page 26, line 23, to page 28, line 11.

The Office Action contends that it is not clear what is encompassed by the term "amphetamine analog" in Claims 53 and 60. The term "analog" is defined in the specification, for example, in the last paragraph on page 7.

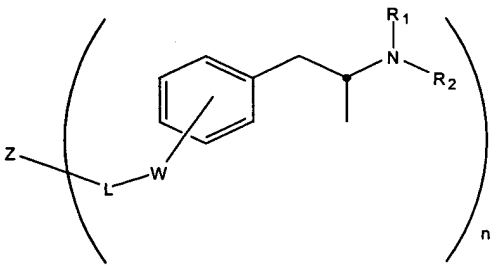
While not acquiescing in the rejection, Applicant's submit that the deletion of the word "about" in Claims 1, 8, 14, 23, 48, 53, 58 and 60 renders the rejection of those cliams moot. The word "about" is not found in Claim 13.

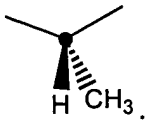
The Office Action alleges that the term "immunogenic protein" in Claims 6, 19, 28, 53 and 60 is confusing. Applicant submits that the amendments to the above claims (with the exception of Claim 28) in this regard obviate this ground of rejection. The term is not found in Claim 28.

Rejection under 35 U.S.C. 102

Claims 1-60 were rejected under 35 U.S.C. 102(b) as being anticipated by Heiman, *et al.* (U.S. Patent No. 5,262,333) (Heiman). Heiman's disclosure relates to a method and reagents for determining amphetamine and d-methamphetamine in a biological fluid, such as urine. In particular, the disclosure relates to improvements in a fluorescence polarization immunoassay procedure for determining the presence of amphetamine and d-methamphetamine in a single assay and to a class of tracer compounds employed as reagents in such procedures. The tracer is a phenylethylamine derivative, which is linked to a fluorescein derivative by, for example, an amido, amidino, triazinylamino, carbamido, thiocarbamido, carbamoyl, thiocarbamoyl, or sulfonylcarbamoyl group. The procedure described includes pretreatment of the biological sample to eliminate cross reactants such as beta-hydroxyphenethylamine by preincubating the sample solely with an aqueous periodate solution having a pH from about 4.0 to about 7.5 without adjustment to an alkaline pH, and contacting the sample with riboflavin binding protein to reduce interference from fluorescent components in the sample. The procedure also maintains the cross reactivity of the immunoassay for tyramine at about 0.4% and for 1-methamphetamine below about 5.1% and eliminates the necessity of using controlled substances as starting materials.

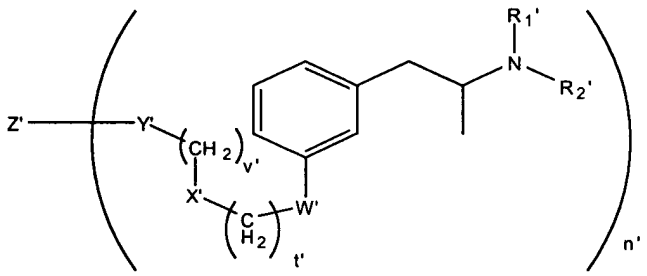
Heiman does not disclose or suggest the compounds of the present claims. Claim 1, for example, is directed to compounds of Formula I:



As indicated in Applicant's specification,  represents  or  .

As can be seen, the compounds of Formula I are stereospecific isomers. Heiman makes no disclosure or suggestion of such compounds. Furthermore, in support of the proposition that the reference discloses the particular compounds of the present claims, the Office Action relies on language in the reference that R is a linking group including up to 5 heteroatoms and having a total of from 0 to 15 carbon atoms and heteroatoms. The aforementioned generic recitation of a group of atoms selected from the group of atoms set forth in the reference does not anticipate or suggest the moieties claimed in Claim 1. The disclosure of the reference is no more than an invitation for one to invent linking groups. Furthermore, the specific disclosure of Heiman of certain linking groups does not include those in the present claims.

Claim 8 is directed to compounds of the formula:



wherein the compound is a stereoisomeric mixture that comprises at least 51% of one stereoisomeric form over the other. Heiman does not disclose or suggest such stereoisomeric mixture of compounds. Furthermore, Heiman does not disclose substitution at the 2-position of the ring.

Claim 12 is directed to a compound according to Claim 8, wherein the stereoisomeric mixture comprises at least 90% of one stereoisomeric form over the other. Again, Heiman's disclosure is devoid of any teaching or suggestion of such compounds.

For reasons set forth above with regard to Claims 1 and 12, Claim 13 is not disclosed or suggested by the teaching of Heiman. Furthermore, as with Claim 8, Heiman does not disclose substitution at the 2-position of the ring.

Other claims depending, either directly or indirectly, from Claim 1 are patentable over Heiman at least as a result of their respective dependency from Claim 1.

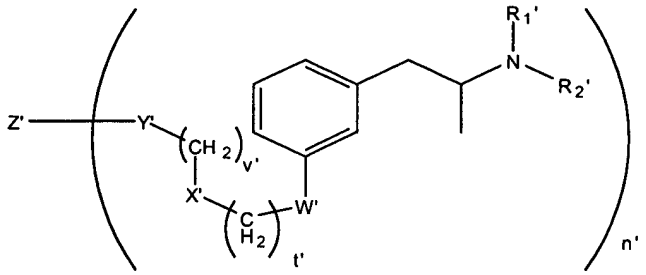
For reasons set forth above with regard to Claims 1, 8, 12 and 13, Claims 14, 23, 48, 53, 58 and 60, and claims depending respectively therefrom, are not disclosed or suggested by the teaching of Heiman.

Heiman does not disclose or suggest the antibodies of Claims 20-22, 29-32, 36, 40, 44, 48, 53, 58 and 60, which are raised against the immunogens as defined. The immunogenic compounds of the claims are not disclosed or suggested by the reference, as discussed above. The Office Action asserts that the antibodies of the above claims are considered functionally equivalent to the antibodies of Heiman because, continues the Office Action, they have the same specificity. However, the antibodies of the present claims are raised against immunogens that are structurally different from the immunogens of the reference. Accordingly, one skilled in the art would expect that the antibodies would have different specificity in that they would recognize a different portion of the amphetamine or methamphetamine molecule.

Claims 1, 3-23 and 25-60 were rejected under 35 U.S.C. 102(a) as being anticipated by Hui, *et al.* (U.S. Patent Publication No. 20030175995) (Hui). The reference discloses compounds including haptens, intermediates, and immunogens that are useful in the production of antibodies specific for the methylenedioxy class of amphetamine derivatives.

Applicant submits that the above claims and claims depending therefrom are patentable over Hui. As mentioned above, the compounds of Formula I are stereospecific isomers. Hui makes no disclosure or suggestion of such compounds.

Claim 8 is directed to compounds of the formula:



wherein the compound is a stereoisomeric mixture that comprises at least 51% of one stereoisomeric form over the other. Hui does not disclose or suggest such stereoisomeric mixture of compounds. Furthermore, Hui does not disclose substitution at the 2-position of the ring.

Claim 12 is directed to a compound according to Claim 8, wherein the stereoisomeric mixture comprises at least 90% of one stereoisomeric form over the other. Again, Hui's disclosure is devoid of any teaching or suggestion of such compounds.

For reasons set forth above with regard to Claims 1 and 12, Claim 13 is not disclosed or suggested by the teaching of Hui. Furthermore, as with Claim 8, Hui does not disclose substitution at the 2-position of the ring.

Other claims depending, either directly or indirectly, from Claim 1 are patentable over Hui at least as a result of their respective dependency from Claim 1.

For reasons set forth above with regard to Claims 1, 8, 12 and 13, Claims 14, 23, 48, 53, 58 and 60, and claims depending respectively therefrom, are not disclosed or suggested by the teaching of Hui.

Furthermore, with regard to Claim 14 and those claims depending therefrom, Hui states that Z is -L-X-Q, L is defined as 1-15 carbon atoms and 0-6 heteroatoms, X is selected from the group consisting of --O--, --CO--, --NR^4--, --S--, --C(=NH)O--, --NH(CO)-- --NH(CO)NH--, --NH(CS)--, --NH(CS)NH--, --O(CO)NH--, --NH(C=NH)--, and maleimidothioether, wherein R^4 is selected from the group consisting of hydrogen and an alkyl group. Q is selected from the group consisting of hydrogen, a hydroxyl, a leaving group, a macromolecular carrier, and a label.

The aforementioned L-X-Q moiety of the reference does not anticipate or suggest the moieties claimed in Claim 14. The disclosure of the reference provides no more than

an invitation for one to invent linking groups. For example, Hui does not disclose or suggest at least the compounds wherein v" is 2 to 6. Hui does not disclose or suggest a linker comprising $\rangle SO_2$ as claimed in Claim 14 and those claims depending therefrom.

The aforementioned L-X-Q moiety of the reference does not anticipate or suggest the moieties claimed in Claim 14. The disclosure of the reference provides no more than an invitation for one to invent linking groups. For example, Hui does not disclose or suggest at least the compounds wherein v" is 2 to 6. Hui does not disclose or suggest a linker comprising $\rangle SO_2$ as claimed in Claim 14 and those claims depending therefrom.

Hui does not disclose or suggest the antibodies of Claims 20-22, 29-32, 36, 40, 44, 48, 53, 58 and 60, which are raised against the immunogens as defined. The immunogenic compounds of the claims are not disclosed or suggested by the reference, as discussed above. The Office Action asserts that the antibodies of the above claims are considered functionally equivalent to the antibodies of Hui because, continues the Office Action, they have the same specificity. However, the antibodies of the present claims are raised against immunogens that are structurally different from the immunogens of the reference. Accordingly, one skilled in the art would expect that the antibodies would have different specificity in that they would recognize a different portion of the amphetamine or methamphetamine molecule.

Claims 1-6 were rejected under 35 U.S.C. 102(b) as being anticipated by Wang, *et al.* (U.S. Patent Publication No. 20020090661 A1) (Wang). The reference discloses tracers and their synthesis and use in an immunoassay for the detection of controlled drugs such as amphetamine (APM), methamphetamine (MAPM) and their derivatives, in a biological or aqueous sample. In particular, the disclosure of Wang provides methods for synthesizing tracers in which a non-controlled substance is both the starting material in tracer synthesis and the binding site on the resulting novel tracer for the antibody, thereby eliminating the necessity of using controlled substances as starting materials. In addition, the tracers of Wang can be used as an analyte analog in an immunoassay, such as a continuous flow displacement immunoassay.

Without acquiescing in the position of the Office action, Applicant submits that Claims 1-6 are patentable over Wang, who fails to disclose or suggest the compounds having L as defined in Claim 1.

Claims 1-4 were rejected under 35 U.S.C. 102(b) as being anticipated by Hu, *et al.* (U.S. Patent No. 5,135,863) (Hu). Without acquiescing in the position of the Office action, Applicant submits that Claims 1-4 are patentable over Wang, who fails to disclose or suggest the compounds having L as defined in Claim 1.

Conclusion

Applicant has demonstrated that Claims 1-6 and 8-60 satisfy the requirements of 35 U.S.C. 112 and 102. Allowance of the above-identified patent application, it is submitted, is in order.

Respectfully submitted,

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